

REMARKS

Claims 1-74 remain in this application. Claims 10, 17 and 35-38 have been amended. Applicants believe that all claims are now allowable, as set forth in more detail below.

As an initial matter, the interviews between the Examiner and attorney for the assignee of the present application, Tong Wu, on October 29 and 31, 2003, is gratefully acknowledged. During the interviews, the Examiner stated that he would issue a replacement Office Action in light of certain defects in the present Office Action. However, as of the date this amendment is being submitted, PAIR indicates that such a replacement Office Action has not yet been issued. Therefore, because the time for response to the current Office Action, dated July 9, 2003, continues to run, the Applicant has decided to submit this Reply, which is as responsive as possible to the Office Action in view of the defects. Regardless of any ambiguity created by the defects, however, the applicants believe that all claims are allowable, as discussed below. If, however, the Examiner does issue another Office Action, Applicant respectfully requests that it not be made "final" in order to allow the Applicant an opportunity to fully develop and present any additional response that may be necessary.

Objection to Drawings

The Examiner objected to drawings because none showed the third probe recited in claim 34. The applicants have submitted new Figure 6, which shows the third probe. Appropriate verbage referring to the new Figure 6 is added to the specification. No new matter has been added.

Amendments to the Specification

The specification is amended to accommodate the new Figure 6 in support of claim 34 by adding new paragraphs [0018A] and [0025A] and to correct a word processing error in paragraph [0026]. No new matter is added.

Claim Rejections-35 U.S.C. § 101

The Examiner rejected claim 13-20 and 25-31 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The Applicants believe the amendments in this reply obviate that issue. The Examiner asserts that because the claims recited that one of the sensors was at a position relative to the lower or upper sphincter or in a specific portion of the esophagus, the claims positively recited human body. However, positively reciting positions of sensors relative to each other that accommodate advantageous spatial relationship to their

operational environment is distinctly different from positively reciting the operational environment itself, in this case parts of the human body. Instead, the recited operational environment imposes certain structural limitations on the claimed system, for example, positioned spatially apart from each other enough to straddle a person's UES as explained in the specification, page 6, line 23-28, and page 7, lines 1-3. Examples of structures that accommodate positioning of the first sensor in relation to the LES and UES are included in the specification, page 6, line 23, through page 7, line 25, which support, but are not intended to limit the scope of, the claims. The lower and upper sphincters and esophagus mentioned in these claims merely specify where the sensors, which *are* positively recited in the claims, are positioned in relation to each other in order for them to perform the desired functions when the probe is in use, and they are not positively recited as claim limitations or components of the invention. Therefore, the Applicant requests that the rejections based on non-statutory subject matter be withdrawn.

Claim Rejections-35 U.S.C. § 112

The Examiner rejected claims 10 and 35-38 under 35 U.S.C. § 112, ¶ 1 as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner objected to the use of the word “bifurcated” in describing the probes because neither probe is disclosed as being branched. Of course, the Applicant was not trying to recite that each of the individual probes is branched, but was simply trying to recite that they are separate branches in relation to each other. The Applicants have amended claim 10 to clarify that the first and second probes extend separately from a common connection, which is intended merely to use different words to recite the same relationship and not to narrow the scope or equivalence coverage of the claim. As to claims 35-38, the word “bifurcated” is only used in the preambles and modifies the word “catheter” and not any of the first and second probes. Nonetheless, the Applicants have removed the word “bifurcated” from claims 35-38 without surrendering any claim scope or range of equivalence, as the use of the word in the preambles is not limiting. Therefore, the Applicant requests that this rejection be withdrawn.

The Examiner further rejected claim 17 under 35 U.S.C. § 112, ¶ 2 as being indefinite because of the recitation that the first sensor is 5 cm from the distal end of the first probe while

claim 15 recites that the first sensor is located proximate the lower esophageal sphincter. The applicants have amended claim 17, as the Examiner suggested, to recite that the *second* sensor is about 5 cm from the distal end of the first probe. The rejection should therefore be withdrawn.

Claim Rejections 35 U.S.C. §§ 102 and 103

The Examiner rejected various claims under 35 U.S.C. § 102 or 103 as either anticipated by, or obvious in light of, the *Shaker* reference (Shaker, R. *et al.*, “Esophagopharyngeal Distribution of Refluxed Gastric Acid in Patients with reflux Laryngitis”, *Gastroenterology*, Vol. 109, pp. 1575-1582 (1995)). Because there are portions of the present Office Action that appear to conflict each other, and there are claims not acted upon, the Applicants are uncertain as to the allowability of several claims. However, applicants believe that all pending claims are now allowable over prior art, as set forth below.

Independent claim 1 requires a recorder be responsive to the signals of at least *two* sensors, each of which is on a separate probe and to *correlate* the signals from the at least two sensors of the separate probes. *Shaker*, in contrast to the present invention, teaches using two *separate* data loggers that have no correlation with each other to record the signals from their respective sensors. *See, e.g., Shaker* at 1576, left column, lines 31-37 and right column, line 23-26. The two data loggers record data from their respectively connected sensors separately and on their own time scales. It is only upon the completion of each study that the signals are transferred to a computer for analysis. *Id.* It is worth noting that even in disclosing this transfer stage, there is no teaching in *Shaker* that the both data loggers are connected to the computer. Thus, there is no teaching in *Shaker* of a recorder that is responsive to both sensors on a single time scale.

Having a recorder that is responsive to signals from two or more sensors is a key feature of the claimed invention and designed to overcome the shortcomings that exist in the prior art, including *Shaker*. In fact, the problems with *Shaker*-type systems, which were state-of-the-art prior to this invention, are specifically addressed in paragraph [0023] of the specification. As discussed in paragraph [0023] on page 8, line 28-page 9, line 9 of the present application, when multiple recorders are used as was done in *Shaker*, a certain margin of error may be introduced to the data. In fact, *Shaker et al.* admit to this kind of problem in their technique and noted that their study subjects had to be asked to go back and indicate correct information when discrepancies were found between information recorded on their data logger and information

provided in the study, subjects diary. See Shaker et al., page 1576, right column, lines 22-26. By using a single recorder that is responsive to multiple sensors according to the present invention, data from the different sensors and other event markers can be accurately recorded and plotted versus elapsed time on a single time scale from a single time clock, with a negligible margin of error. See Specification, paragraph [0023].

Thus, the invention recited in claim 1 is neither anticipated by *Shaker*, nor obvious in light of *Shaker*, alone or in combination with other cited references.

Similarly, independent claim 35 requires that the second sensor arrangement be configurationally associated with the first sensor arrangement and that a recorder be responsive to both sensors. Thus, based the same argument advanced above, claim 35 is neither anticipated by *Shaker*, nor obvious in light of *Shaker*, alone or in combination with other cited references.

Independent method claim 42 requires receiving at least two signals from different portions of the body at a recorder and correlating the signal with the recorder. Based on the same argument advanced above, claim 35 is neither anticipated by *Shaker*, nor obvious in light of *Shaker*, alone or in combination with other cited references.

Likewise, independent method claim 74 requires *integratively* receiving two signals and correlating the two signals. Based on the same argument advanced above, claim 35 is neither anticipated by *Shaker*, nor obvious in light of *Shaker*, alone or in combination with other cited references.

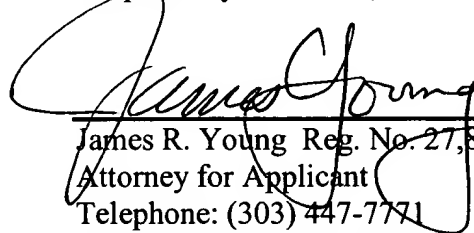
Each of the remaining claims is ultimately dependent on one of the above-discussed independent claims and, because of the additional advantages the claimed invention offers, is neither anticipated by *Shaker*, nor obvious in light of *Shaker*, alone or in combination with other cited references.

Finally, the method claims 42-46, 48, 50, 53, 58-60, 62, 64-65, and 68-74 are amended to delete recitations of "steps" to avoid any presumptions of narrow claim construction under 35 U.S.C. § 112, sixth paragraph.

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If any issues remain to be resolved, the examiner is requested to contact applicant's attorney at the telephone number listed below.

No fee is believed to be necessary. Should any fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "James R. Young", is written over a horizontal line.

James R. Young Reg. No. 27,847
Attorney for Applicant
Telephone: (303) 447-7771
Facsimile: (303) 447-7800

Dated: December 4, 2003

BLDR1:50202458.01